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NEW JERSEY, CHEMICAL INDUSTRY CRITIQUE ATSDR'S DRAFT PFC RISK ANALYSES

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Abstract: Scientists working for the state of New Jersey and chemical companies are questioning core elements of a federal toxicology profile for 13 perfluoroalkyl chemicals (PFCs), arguing the Agency for Toxic Substances and Disease Registry (ATSDR) has ignored EPA risk assessment policies in calculating two risk estimates but differing on which policies have not been followed.

Full text: Scientists working for the state of New Jersey and chemical companies are questioning core elements of a federal toxicology profile for 13 perfluoroalkyl chemicals (PFCs), arguing the Agency for Toxic Substances and Disease Registry (ATSDR) has ignored EPA risk assessment policies in calculating two risk estimates but differing on which policies have not been followed.

Scientists with New Jersey's departments of Environmental Protection (NJDEP) and Health (NJDOH) call ATSDR's document "inadequate in many instances. The document has not been appropriately updated throughout," the state agencies write in their joint Nov. 25 comments. New Jersey also considers the minimum risk level (MRL) that ATSDR calculated for one of the more researched PFCs, perfluorooctanoic acid (PFOA), "not scientifically supportable. This study does not appear to be an appropriate basis for MRL development, and the Benchmark Dose [BMD] modeling used to derive the MRL is not valid." Relevant documents are available on InsideEPA.com. (Doc. ID: 187771)

And New Jersey harshly critiques the monkey study ATSDR used as the basis for the PFOA MRL calculation. "The study itself is problematic for use in risk assessment for reasons including possible mortality at the lowest dose."

New Jersey's comments, like the rest of the public comments that ATSDR received regarding the draft PFC ToxProfile, were due Dec. 1 but were not released until Dec. 29 at Risk Policy Report's request.

New Jersey also questions ATSDR's mathematical approach, using BMD modeling with the study data, which New Jersey suggests does not follow EPA's BMD modeling technical guidance because ATSDR has "an insufficient number of data points for BMD modeling," relying on a single study. EPA's 2002 guidance on using BMD modeling "would instead recommend use of a" no observed adverse effect level or lowest adverse effect level derivation when only one dose group is available, the state says.

The state does not comment upon the study that ATSDR uses as the basis for its MRL for another more-researched PFC, perfluorooctane sulfonate (PFOS).

Industry comments criticize ATSDR's MRL for both PFOA and PFOS, questioning the federal agency's decision to base the MRLs on liver weight change effects, which they argue does not comport with EPA risk assessment guidance.

For example, 3M writes in its Nov. 30 comments that "The selection of these two MRLs was based on the increased liver weight observed in non-human primate toxicology studies, which, based on guidance, research and the comments provided herein, is scientifically unjustified. The use of increased liver weight alone by the ATSDR is inconsistent with current USEPA guidelines and other published peer-reviewed expert conclusions." 3M goes on to argue that the liver weight effects ATSDR uses to calculate the risk estimates are reversible and argues that "a significant body of mechanistic experimental data that relates to the liver response to exposure to PFOA or PFOS strongly suggests that liver weight as an endpoint for the human-health risk assessment is inappropriate and needlessly conservative."

An environmentalist in a critique of ATSDR's draft when it was released last fall bemoaned its reliance on liver weight change, which is often a crude assessment of an agent's toxicity. Newer studies assess PFCs'

reproductive developmental toxicity, as well as its immunotoxicity, the source said, pointing specifically to a recent review article by Philippe Grandjean and Richard Clapp, public health professors at Harvard University and University of Massachusetts Lowell, respectively. The source said he hopes that EPA's water office, in finalizing its ongoing assessments of PFOA and PFOS, chooses not to follow ATSDR's approach.

ATSDR, by congressional mandate, produces ToxProfiles for hazardous substances found at Superfund sites, based on frequency of occurrence, toxicity and potential for human exposure. The agency also produces profiles for substances related to sites connected with the Defense and Energy departments.

The draft ToxProfile for 13 PFCs, released for public comment in September, includes non-cancer risk estimates for PFOA and PFOS that are similar to EPA's Integrated Risk Information System (IRIS) risk estimates. But the new draft document does not contain risk calculations for the other 11 PFCs because ATSDR determined that it had insufficient information to calculate quantitative risk estimates for them – a finding that industry supports but the New Jersey scientists say is unfounded.

For PFOA, ATSDR calculates an MRL for intermediate exposure duration of 2×10^{-5} milligrams per kilogram bodyweight per day (mg/kg/day), based on a 2002 study showing liver weight changes in lab monkeys. For PFOS, ATSDR proposes an MRL of 3×10^{-5} mg/kg/day, based on liver weight changes in a separate 2002 toxicology study of lab monkeys.

ATSDR calculates MRLs for acute, intermediate and chronic exposure durations by ingestion or inhalation, while EPA's IRIS program generally focuses on chronic risk estimates by either route of exposure.

In the case of PFOA and PFOS, ATSDR provides only intermediate-duration oral MRLs, defined in the document as exposure durations of 15-364 days. Because of the difference in the duration of the risk estimates, the numbers cannot be compared directly to the chronic IRIS reference doses that EPA proposed for PFOA and PFOS in its latest draft assessment, which underwent critical peer review in August of 2014.

EPA's Office of Water in 2009 issued drinking water health advisory levels of 0.4 micrograms per liter of water (ug/L) for PFOA and 0.2 ug/L for PFOS, but these numbers are not mandatory. Based on standard default assumptions EPA uses for its drinking water standards and health advisories, the PFOA reference dose (RfD), for example, would appear to translate into a chronic drinking water health advisory level of 0.1 ug/L, a stricter level than the 2009 health advisory level.

EPA in 2014 proposed a PFOA RfD, the maximum amount of a substance EPA estimates can be ingested daily over a lifetime without adverse non-cancer health effects, of 2×10^{-5} mg/kg/day due to changes in the liver linked to developmental effects and changes in the kidney. In the PFOS assessment, EPA is proposing an RfD of 3×10^{-5} mg/kg/day due to developmental toxicity and liver effects (Risk Policy Report, Sept. 8).

EPA, meanwhile, announced last month that it plans to conduct an IRIS assessment of perfluoroalkyl compounds, though its agenda indicates that managers are still discussing which of the compounds will be included in the IRIS assessment. The assessment is in the first group of chemicals that EPA has prioritized for starting to assess in the next few years (Risk Policy Report, Dec. 22).

Commenting on ATSDR's decision to limit risk estimates in the ToxProfile to PFOA and PFOS, the New Jersey scientists say "ATSDR's conclusion that there is insufficient information to develop MRLs for [PFCs] other than PFOA and PFOS is closely related to its decision that rodent toxicology data, in general, should not be considered for MRL development . . . [but] we do not agree that this conclusion is supported by the available scientific information."

Industry, by contrast, supports this conclusion. For example, consultants to Solvay Specialty Polymers USA, LLC, write in that company's Nov. 30 comments that they agree that with ATSDR's determinations that there are insufficient data to derive acute or chronic MRLs, and that there is only sufficient data to calculate the two subchronic MRLs for PFOA and PFOS. Further, they write that they agree with ATSDR's conclusions that "[f]or all [PFCs], rodent data are not appropriate for use in the evaluation of human health effects and calculation of human health toxicity values [and] . . . [f]or all [PFCs], the human data are insufficient for making clear

determinations of human health risks."

Solvay's comments are supported by the chemical trade organization Chemistry Council of New Jersey, of which Solvay is a member, according to the Council's Dec. 1 comments.

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